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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,141	08/14/2002	Marilyn D Resh	D6272	9735

7590 11/01/2004  
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EXAMINER

HENLEY III, RAYMOND J

ART UNIT PAPER NUMBER

1614

DATE MAILED: 11/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/089,141

**Applicant(s)**

RESH ET AL.

**Examiner**

Raymond J Henley III

**Art Unit**

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8,9 and 15 is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☒ Claim(s) 6 and 7 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

**CLAIMS 1-9 AND 15 ARE PRESENTED FOR EXAMINATION**

Applicants' Amendment filed September 23, 2004 has been received and entered into the application. Accordingly, the specification at page 1 and claims 1, 3-9 and 15 have been amended. Applicants have indicated at page 5 of the amendment that claims 12-14 and 16 have been canceled. However, as shown on pages 2-3 of the amendment, claims 10 and 11 have also been canceled.

In light of the amendments, the objection to the specification and claims and rejections under 35 U.S.C. §§ 112, first and second paragraphs, 102(b) and 103 as set forth in the previous Office action dated June 22, 2004 at pages 2-5 are withdrawn.

***Claim Rejection - 35 USC § 102***

Claims 1 and 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Harper et al., already of record, for the reasons of record as set forth in the previous Office action at page 4, as applied to claims 8, 10-12 and 16.

Applicants' amendment to claim 1 deleting "in need of such treatment" necessitated this new ground of rejection, i.e., the host of claim 1 now is the same host as in Harper et al.

***Claim Rejection - 35 USC § 103***

Claims 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Harper et al. for the reasons of record as set forth in the previous Office action at pages 4 and 5, as applied to claims 8-16.

***Response to Arguments***

Applicants' arguments at pages 8-12, to the extent they are applicable to the new grounds of rejection, have been carefully considered, but fail to persuade the Examiner of error in his determinations of anticipation and obviousness.

It remains the Examiner's position that the mechanisms of action recited in the present claims are inherent in the method taught by Harper et al. Applicants disagree with this position and argue:

"Applicants strongly disagree with the Examiner's statement that inhibiting T-cell signaling events is inherent in the prior art method because the same host is administered the same active agent. One of ordinary skill in the art could not recognize that the prior art inherently produced Applicants' invention." (amendment at page 9).

The Examiner cannot afford this position the significance urged because it is well settled that it is *not* required that those of ordinary skill in the art recognize the inherent characteristics or the function of the prior art, *MEHL/Biophile*, 192 F.3d at 1365, 52 U.S.P.Q.2d at 1303. The discovery of the mechanism underlying a known process does not make it patentable.

Applicants have further argued that:

"Additionally, inherency requires that the result must be a necessary consequence of what is intended. Inhibition of T-cell receptor mediated signaling events is not a necessary consequence of treating a herpes virus infection." (amendment at page 9).

The Examiner agrees that for inherency, the result must be a necessary consequence and not merely a possibility. Applicants' argument, however, is not persuasive because Applicants have not provided a factual basis for their conclusion that the inhibition of T-cell receptor mediated signaling events is not a necessary consequence of treating a herpes virus infection.

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***Overcoming the Above Rejections***

Applicants may wish to consider incorporating claim 6 into claim 1 in order to overcome the above rejections. A subject having an autoimmune disorder is not taught by Harper et al. and thus the concept of inherency would not be applicable.

***Claim Objection***

Claims 6 and 7 are objected to as depending from a rejected base claim, but are otherwise in condition for allowance.

***Allowable Subject Matter***

Applicants' amendments have placed claims 8, 9 and 15 in condition for allowance.

Applicants' amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

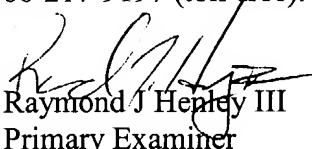
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Raymond J Henley III  
Primary Examiner  
Art Unit 1614

October 29, 2004